DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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November 2, 2016

Limacorporate S.p.A.
% Stephen J. Peoples, VMD, MS
Peoples and Associates Consulting, LLC
5010 Lodge Pole Lane
Fort Wayne, Indiana 46814

Re: K133349
Trade/Device Name: SMR TT Metal Back Glenoid
Regulation Number: 21 CFR 888.3660
Regulation Name: Shoulder joint metal/polymer semi-constrained cemented prosthesis
Regulatory Class: Class II
Product Code: PHX, KWS, KWT
Dated: April 24, 2014
Received: May 2, 2014

Dear Dr. Peoples:

This letter corrects our substantially equivalent letter of June 3, 2014.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Lori A. Wiggins -S

for
Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): ~~Unknown~~ – K133349
Device Name: SMR TT Metal Back Glenoid
Indications for Use:

SMR TT Metal Back Glenoid
Indications for Use

The SMR TT Metal Back Glenoid is intended for use in total primary or revision shoulder joint replacement with either the SMR Anatomic Shoulder System or the SMR Reverse Shoulder system.

The SMR Anatomic Shoulder System is indicated for patients suffering from disability due to:

- Non-inflammatory degenerative joint disease including osteoarthritis and avascular necrosis;
- Inflammatory degenerative joint disease such as rheumatoid arthritis;
- Treatment of acute fractures of the humeral head that cannot be treated with other fracture fixation methods;
- Revision of a failed primary implant;
- Cuff tear arthropathy (CTA Heads);

When used as part of the SMR Anatomic Shoulder System, the SMR TT Metal Back Glenoid is intended for use with bone cement and should be used without bone screws.

The SMR Reverse Shoulder System is indicated for primary, fracture or revision total shoulder replacement in a grossly rotator cuff deficient joint with severe arthropathy (disabling shoulder). The patient's joint must be anatomically and structurally suited to receive the selected implants and a functional deltoid muscle is necessary to use the device.

When used as part of the SMR Reverse Shoulder System, the SMR TT Metal Back Glenoid is intended for uncemented use with the addition of screws for fixation.

Prescription Use X (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

JUN 0 3 2014

Summary of Safety and Effectiveness

Date: October 8, 2013

Manufacturer:
Limacorporate S.p.A.
Via Nazionale, 52
33038 – Villanova di San Daniele
Udine - Italy

U.S. Contact Person:
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Product	Common Name	Product Code	Regulation and Classification Name
SMR TT Metal Back Glenoid	Total or Hemi Shoulder Prosthesis	KWS	Shoulder joint metal/polymer semi-constrained cemented prosthesis per 21 CFR 888.3660
		KWT	Shoulder joint metal/polymer non-constrained cemented prosthesis per 21 CFR 888.3650

Description:

The SMR TT Metal Back Glenoid is nearly identical to the design of the SMR Modular Glenoid component cleared for use in anatomic shoulder replacement as part of the SMR Anatomic Shoulder System (K113254) and for use in reverse shoulder replacement as part of the SMR Reverse Shoulder System (K110598) except that the subject device is a 2-piece modular rather than a 1-piece design. The subject TT Metal Back Glenoid consists of two (2) components, a baseplate and a peg, that are coupled together and placed in the prepared glenoid cavity. When used as part of the SMR Anatomic Shoulder System (K113254), the subject SMR TT Metal Back Glenoid attaches to the SMR Anatomic Shoulder System's Modular Glenoid Liner component and is intended for use with bone cement. When used with the SMR Reverse Shoulder System (K110598), the subject SMR TT Metal Back Glenoid attaches to the SMR Reverse Shoulder Glenosphere component (K110598) and is intended for uncemented fixation, with additional fixation provided by bone screws. In the SMR Reverse Shoulder System application, the SMR TT Metal Back Glenoid is attached to the SMR Reverse Shoulder Glenosphere using the connectors cleared in K110598.

Baseplates are made from Ti6Al4V and are available in three sizes (Small-R, Small and Standard) while Pegs are manufactured using an EBM (Electron Beam Melting) process

with titanium alloy powder (Ti6Al4V, ASTM F1472 – ISO 5832-3). Pegs are characterized by a conical coupling to allow the connection with baseplates. They present a Trabecular Titanium structure on the external surface.

Liners to be used coupled to SMR TT Metal Backs in anatomic constructs have been cleared via K113254.These devices are intended articulate with previously cleared SMR standard or CTA humeral heads (K110858 and K110847).

Bone screws, Glenospheres and connectors have been cleared via K110598.

Intended Use:

The SMR TT Metal Back Glenoid is intended for use in total primary or revision shoulder joint replacement with either the SMR Anatomic Shoulder System or the SMR Reverse Shoulder system.

The SMR Anatomic Shoulder System is indicated for patients suffering from disability due to:

Non-inflammatory degenerative joint disease including osteoarthritis and avascular necrosis;
Inflammatory degenerative joint disease such as rheumatoid arthritis;
Treatment of acute fractures of the humeral head that cannot be treated with other fracture fixation methods;
Revision of a failed primary implant;
Cuff tear arthropathy (CTA Heads);

When used as part of the SMR Anatomic Shoulder System, the SMR TT Metal Back Glenoid is intended for use with bone cement and should be used without bone screws.

The SMR Reverse Shoulder System is indicated for primary, fracture or revision total shoulder replacement in a grossly rotator cuff deficient joint with severe arthropathy (disabling shoulder). The patient's joint must be anatomically and structurally suited to receive the selected implants and a functional deltoid muscle is necessary to use the device.

When used as part of the SMR Reverse Shoulder System, the SMR TT Metal Back Glenoid is intended for uncemented use with the addition of screws for fixation.

Predicate Devices:

SMR Modular Glenoids (Limacorporate, K113254):
Delta Xtend Reverse Shoulder System (DePuy, K120174);
Aequalis Reversed Shoulder Prosthesis (Tornier, K100142-K081059).

Comparable Features to Predicate Device(s):

The SMR TT Metal Back Glenoid is similar to the predicate devices in terms of intended use, indications, design and materials. The SMR TT Metal Back Glenoid and the predicates are all intended for total primary or revision shoulder joint replacement.

Traditional 510(k) – SMR TT Metal Back Glenoid

Fixation methods for the SMR TT Metal Back Glenoid depend on whether it is being used with an Anatomic or Reverse Shoulder System. These fixation methods are similar to those for the predicate Anatomic and Reverse Shoulder Systems.

The SMR TT Metal Back Glenoid has a design which is similar to the metal-back glenoid of the SMR Modular Glenoid (K113254) except that the subject device is a 2-piece modular rather than a 1-piece design. Like the SMR Modular Glenoid (Limacorporate), the liner-metal back coupling is achieved through a snap-fit junction.
The components of the SMR TT Metal Back Glenoid are manufactured from the same or similar materials as the predicate devices.

Non-Clinical Testing:

The SMR TT Metal Back Glenoid was tested for fatigue resistance of the modular connection between the baseplate and the peg. The connection between the Metal Back and the Liner has not been changed from the one of the SMR Modular Glenoids. Mechanical testing was performed on worst case components or constructs. The testing results demonstrated the device's ability to perform under expected clinical conditions.

Clinical Testing:

Clinical testing was not necessary to demonstrate substantial equivalence of the SMR TT Metal Back Glenoid to the predicate devices.